Section 3 510(k) Summary

This 510(k) Summary of 510(k) information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: 11/04/2013

2. Sponsor Identification

Changzhou Dean Medical Instrument Co., Ltd.
No. 10, Jinshajiang Road, Xinbei District, Changzhou, Jiangsu, 213125, China

Establishment Registration Number: Not yet registered

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3. Submission Correspondent

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4. Proposed Device Identification

Common Name: Locking Bone Plates and Locking Bone Screws
Proposed Device Name: Locking Compression Bone Plates and Screws System

Plate:
Classification Name: Plate, Fixation, Bone
Common Name: Bone Plates
Class: Class II
Product Code: HRS
Regulation Number: 21 CFR 888.3030
Review Panel: Orthopedic

Screw
Classification Name: Screw, Fixation, Bone
Common Name: Bone Screws
Class: Class II
Product Code: HWC
Regulation Number: 21 CFR 888.3040
Review Panel: Orthopedic

Intended Use Statement:
The Locking Compression Bone Plates and Screws System can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius and tibia.

5. Predicate Device Identification

510(k) Number: K131759
Product Name: Metallic Locking Compression Bone Plates and Screws System
Manufacturer: Tianjin Walkman Biomaterial Co., Ltd

6. Device Description

The proposed product, Locking Compression Bone Plates and Screws System, contains (1) locking compression plates (LCPs) with various specifications, (2) locking screws with various specifications and (3) various specific instruments.

The locking compression plates are used for internal fixation of bones, screws are used for fix the plates on the bones, and instruments are used for completing the surgery.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM F382-99 (Reapproved 2008), Standard Specification and Test Method for Metallic Bone Plates;
ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device K131759
Product Code	HRS	HRS
	HWC	HWC
Regulation Number	21 CFR 888.3030	21 CFR 888.3030
	21 CFR 888.3040	21 CFR 888.3040
Intended Use	Locking Compression Bone Plates and Screw System is intended for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius and tibia.	Metallic Locking Compression Bone Plate and Screw System is intended for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur and tibia.
Material	Bone Plate: Titanium	Bone Plate: Titanium
	Locking Screw: Titanium alloy	Locking Screw: Titanium alloy
How supplied	Non-Sterile	Non-Sterile
Single Use	Yes	Yes
Sterile	Subject to steam sterilized prior to use.	Subject to steam sterilized prior to use.
Performance	Static and Dynamic Performance tested per ASTM F382 Torsional, Driving Torque and Pull out strength tested per ASTM F543.	Static and Dynamic Performance tested per ASTM F382 Torsional, Driving Torque and Pull out strength tested per ASTM F543.

Differences in physical specification and performance between the proposed and predicate device have been discussed and address. The proposed device is determined to be Substantially Equivalent (SE) to the predicate device, in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 4, 2014

Changzhou Dean Medical Instrument Co., Ltd.
% Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China

Re: K133525
Trade/Device Name: Locking Compression Bone Plates and Screws System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: February 7, 2014
Received: February 10, 2014

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent P. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Indications for Use

510(k) Number: K133525

Device Name: Locking Compression Bone Plates and Screws System

Indications for Use:

The Locking Compression Bone Plates and Screws System can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius and tibia.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

OR

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Frank -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133525